



The European Association Medical
Devices - Notified Bodies

TEAM-NB A.I.S.B.L.
Boulevard Frère Orban 35A
B – 4000 Liège BELGIQUE
Tél.: + 32 (0)4 254 55 88
Fax: + 32 (0)4 254 55 89

E-mail: secretary@team-nb.org
Web: <http://www.team-nb.org>
Bank ING: 340-1517487-57
IBAN BE09 3401 5174 8757

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Position paper on the future negotiations on the new legislation for Medical Devices.	

Team-NB, the European Association for Medical Devices of Notified Bodies, welcomes the agreement reached by the Council in June 2015 on the two draft pieces of legislation on Medical Devices and In Vitro Diagnostic Medical Devices. As the two proposals have been tabled by the Commission almost three years ago, TEAM-NB hopes that the negotiations between the Council and the Parliament will be concluded quickly. TEAM-NB especially expresses its satisfaction to see the two files being considered by the Luxemburgish Presidency of the Council as priority.

TEAM-NB has always advocated a regulatory framework which strengthens the conformity assessment and market surveillance. It is necessary to learn from the problems of the past and to improve the control system. In this context, TEAM-NB wishes to highlight three issues which still need to be solved during the future negotiations and where it is necessary to find a well-balanced compromise, raising the standards and keeping a reasonable burden on the actors.

TEAM-NB and its members are willing, ready and prepared to support legislators in this crucial phase of the legislative process and to provide their expertise on future wordings of the regulations in order to assess its potential impact on the medical landscape.

1. Authorised Representatives.

Today, a lot of Notified Bodies and market surveillance authorities are facing problems with “ghost” Authorised Representatives developing bad practices, disappearing after a short existence (mostly some months) and reappearing shortly afterwards. This problem must be addressed in an efficient way. Giving Authorised Representatives of non EU-manufactures the full liability for defective devices, as the Council is suggesting it in the new paragraph 4a of article 9 will not contribute to solve the problem but will make things even worse. It will make it unattractive for a lot of small and medium economic players to remain or become Authorised Representatives and will increase the number of “ghost” representatives.

TEAM-NB calls on the institution to delete the wording of the Council in the new paragraph 4a of article 9.

2. Distinction between the Notified Bodies

The proposals of the Parliament and the Council differ in their wordings but have in common the idea of distinguishing between Notified Bodies and to provide different Notifications or extra Notifications according to the classification of the devices.

TEAM-NB fully supports the idea of improving requirements towards Notified Bodies. This has also been done at our level, by developing and enforcing our code of conduct. Since

several years, notification requirements have been increased by national authorities. Joint audits make sense and it is necessary to require more from our work.

However, any extra-notification should focus on sectors rather than on classes. It is frequent for manufacturer to have framework contracts with Notified Bodies for the conformity assessment of several devices of several classes. An extra notification only for class III would not make things easier.

3. Scrutiny

TEAM-NB agrees that there is a need to review and strengthen the scrutiny, especially on class III devices. In this context, it is important to reinforce already existing mechanisms of pre-market authorisations (conformity assessment carried out by Notified Bodies) rather than destroying a whole system.

Any pre-market scrutiny by national authorities must be harmonised between the two legislations and complementary to the work of Notified Bodies. TEAM-NB is willing and ready to provide expertise to the institutions in order to define such a procedure.